

UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

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March 4, 1988

Mr. Ronald Wilson Health Assessment Policy Staff Office of Health Affairs Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,284,647, issued August 18, 1981, was filed on February 22, 1988 under Title II of Public Law 98-417.

The assistance of your Office is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC 156 (g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a process of using a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 USC 156.

C.E.Valton

Charles E. Van Horn
Deputy Solicitor
U.S. Patent and Trademark Office

Donald J. Bird, Esq.
Cushman, Darby & Cushman
1615 L Street, N.W.
11th Floor
Washington, D.C. 20036-5601